K140539

JUN 09 2014

Kimberly-Clark Corporation

510K Summary

Date Summary was Prepared:	May 8, 2014
510(k) Submitter:	David M. Lee, JD Associate Director of Regulatory Affairs Kimberly-Clark Health Care 1400 Holcomb Bridge Road Bldg. 300/1 Roswell, GA 30076 770-587-7167 David.m.lee@kcc.com
Primary Contact for this 510(k) Submission:	David M. Lee, JD Associate Director of Regulatory Affairs Kimberly-Clark Health Care 1400 Holcomb Bridge Road Bldg. 300/1 Roswell, GA 30076 770-587-7167 David.m.lee@kcc.com
Device Trade Name:	Aero Blue* Performance Surgical Gowns
Device Common Names	Surgical Gown
Device Product Codes and Classification Names:	FYA Class II Surgical Gown
Predicate Devices	The Aero Blue* Performance Surgical Gowns under submission are substantially equivalent to the predicate device, the Microcool Breathable High Performance Surgical Gowns (K103406).
Device Description:	A Spunbond/Film/Spunbond/Meltblown/Spunbond design (SFSMS) that provides AAMI Level 3 liquid barrier protection in the critical zone of the gown. The back of the gown is a SMS (spunbond/meltblown/spunbond fabric that is air-breathable and provides AAMI Level 1 liquid barrier protection.

Intended Use:

The **Aero Blue* Performance Surgical Gowns** are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The Aero Blue* Performance Surgical Gowns meet the Level 3 requirements of the AAMI PB70: 2012 Liquid Barrier classifications.

The **Aero Blue* Performance Surgical Gowns** are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.

Technological Characteristics and Substantia Equivalence:

The Kimberly-Clark* **Aero Blue* Performance Surgical Gowns** are substantially equivalent to the predicate device, the Microcool Breathable High Performance Surgical Gowns (K103406), in intended use, design, performance and manufacturing processes. Both gowns incorporate a film laminate fabric in the gown critical zone. The primary differences are that the **Aero Blue* Performance Surgical Gowns** provide AAMI PB70:2012 Level 3 liquid barrier protection in the critical zone, while the predicate gown provides AAMI Level 4 protection, and the **Aero Blue* Performance Surgical Gowns** incorporate in the back of the gown a breathable SMS fabric providing AAMI Level 1 protection. **The Aero Blue* Performance Surgical Gowns** fabric in the critical zone also complies with ASTM F-1670-08 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood. The above differences in design and AAMI liquid protection level raise no new issues of safety and efficacy since the **Aero Blue* Performance Surgical Gowns** are designed, tested, and labeled in compliance with the AAMI PB70: 2012 Liquid Barrier Level 3 liquid barrier requirements.

Summary of Non-Clinical Testing:

The **Aero Blue* Performance Surgical Gowns** have been tested for compliance in the critical zone with the requirements of Level 3 liquid barrier performance requirements of ANSI/AAMI PB70: 2012 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities". The back of the gown, which is in the non-critical zone, provides ANSI/AAMI PB70: 2012 Level 1 liquid barrier protection. The **Aero Blue* Performance Surgical Gowns** also meet **ASTM F1670-08**; Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood in the critical zone fabric. The **Aero Blue* Performance Surgical Gowns** also meet the requirements of Flame Resistant CPSC 1610 Class 1. The **Aero Blue* Performance Surgical Gown** has also been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces. The **Aero Blue* Performance Surgical Gowns** are also tested in compliance with ISO 11810 for resistance to laser ignition.

All results of testing met acceptance criteria

Summary of Non-Clinical Testing

Standard or Reference	Test Method	Data Generated	Meets Requirement
Standard for the Flammability for Clothing Textiles	16 CFR 1610	Flammability	Pass
ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5:	Cytotoxicity	Cytotoxicity	Pass
ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10	Skin Irritation Study	Irritation	Pass
ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10	Sensitization Test	Sensitization	Pass
ISO 10993-7:2008, Ethylene Oxide sterilization residuals	EO residuals	EO residuals	Pass
Laser Ignition Resistance	ISO 11810-1 (2005)	Laser resistance	Pass
Spray Impact (critical zones)	AATCC 42:2007	Water resistance	Pass
Liquid Barrier Performance	AAMI PB70:2012 Level 3	Water Resistance	Pass
Hydrostatic Head (critical zones)	AATCC 127:2008	Water resistance	Pass
Spray Impact (non- critical zones)	AATCC 42:2007	Water resistance	Pass
Grab Tensile, Peak Stretch, and Peak Energy – Nonwovens	ASTM D5034 (2009)	Tensile Strength	Pass
Abrasion Resistance and Surface Bonding of SMS Laminates	WSP 20.5 (2008)	Abrasion resistance	Pass
Synthetic Blood Penetration	ASTM-1670-08 (2008)	Resistance to penetration	Pass
Mass Per Area (Basis Weight) of Materials	*D3776 (2009)*	Fabric basis weight	Pass
Water Vapor Transmission Rate Through Nonwovens and Plastic Films	WSP 70.4 (2008)	Water Vapor Transmission	Pass
Degree Peel Strength of Laminated Nonwovens – Raw Materials	STM-00197(2010)	Peel Strength	Pass
Resistance to Linting Dry Particle Generation	INDA WSP 160.1 (2009)	Particulate	Pass

Substantial Equivalence Table

Attribute	**Predicate Device: Kimberly-Clark*MicroCool* Breathable High Performance Surgical Gown K103406, (AAMI Liquid Barrier Level 4)**	**Subject of this 510(k): K140539 Aero Blue* Performance Surgical Gown, (AAMI Liquid Barrier Level 3)**
Indications for Use	Kimberly-Clark* MicroCool* Surgical Gowns, are sterile, single use surgical apparel intended to be worn by healthcare professionals to help	Aero Blue* Surgical Gowns, are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the

Attribute	Predicate Device: Kimberly-Clark*MicroCool* Breathable High Performance Surgical Gown K103406, (AAMI Liquid Barrier Level 4)	Subject of this 510(k): K140539 Aero Blue* Performance Surgical Gown, (AAMI Liquid Barrier Level 3)
	protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The MicroCool* Surgical Gown meet the Level 4 requirements of the AAMI Liquid Barrier classifications. The Kimberly-Clark* MicroCool* Surgical Gowns, are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.	patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The Aero Blue* Performance Surgical Gowns meet the Level 3 requirements of the AAMI PB70: 2012 Liquid Barrier classifications. The Aero Blue* Surgical Gowns, are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.
How supplied	Sterile (10^{-6}) or bulk non-sterile	Same
Sterilization Method	Ethylene Oxide	Same
SAL	10^{-6}	Same
Gown color	Blue	Same
Gown sizes	Small, Large, X-Large, XX-Large, XXX-Large	Same
Construction Overview	The MicroCool* Breathable High Performance Surgical Gown is manufactured from a breathable, repellent, non-woven, polypropylene fabric. The gown is constructed from a spunbond/film/spunbond/meltblown/spunbond (SFSMS) design that is adhesively laminated. The gown meets AAMI-4 liquid barrier requirements	The Aero Blue* Performance Surgical Gown under submission is manufactured from a moisture-vapor breathable, repellent, non-woven fabric using a polymer blend of polypropylene and polyethylene. The front body and sleeve fabric is a three layer film laminate. This fabric is an SFSMS design Spunbond/ Film/Spunbond-Meltblown-Spunbond that is adhesively bonded together. Front of Gown meets meet AAMI-3 liquid barrier requirements, while back of Gown in the non-critical zone is composed of a breathable SMS fabric with an AAMI level 1 liquid barrier protection
Does not contain Natural Rubber Latex	Yes	Same

Performance Testing	ANSI/AAMI PB70: 2003 Level 4 Liquid Barrier Requirements - **Pass**	**N/A**
	ANSI/AAMI PB70: 2012 Level 3 Liquid Barrier Requirements – **N/A**	ANSI/AAMI PB70: 2012 Level 3 Liquid Barrier Requirements - **Pass**
	RTM – 6405/STM00204/WSP 70.4 2008 -Water Vapor Transmission Rate of Materials - **Pass**	Same
	RTM 6176/WSP 160.1 2009 - Test Method for Resistance to Linting – **Pass**	Same
	ASTM D 5034 – 2009 Standard Test Method For Breaking Strength and Elongation of Textile Fabrics (Grab Test) - **Pass**	Same
	Peel Strength - EQ-STM 5671/STM00197 2010 – **Pass**	Same
	Hydrohead Low Surface Tension EQ-STM 4507-2012 **Pass**	Same
	STM- 00149 (ASTM-4966/WSP 20.5 2008, Abrasion Test - **Pass**	Same
	Biocompatibility - **Pass**	Same
	16 CFR, Chapter II--Consumer Product Safety Commission Part 1610 -Standard For The Flammability of Clothing Textiles Class I - **Pass**	Same

Conclusion The performance testing submitted for the **Aero Blue* Performance Surgical Gowns** demonstrates substantial equivalence to the predicate Kimberly Clark* Microcool* Breathable High Performance Surgical Gown **(K103406)** in intended use, design, materials, performance and biocompatibility attributes.

*Registered Trademark or Trademark of Kimberly-Clark Worldwide, Inc. or its affiliates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-000

June 9, 2014

Kimberly-Clark Corporation
David M. Lee, JD
Associate Director of Regulatory Affairs
Bldg. 300/1
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K140539
Trade/Device Name: Aero Blue Performance Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Gown
Regulatory Class: Class II
Product Code: FYA
Dated: May 8, 2014
Received: May 9, 2014

Dear Mr. Lee,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017 *See PRA Statement on last page.*

510(k) Number *(if known)*

K140539

Device Name

Aero Blue* Performance Surgical Gowns

Indications for Use *(Describe)*

Intended Use: The **Aero Blue* Performance Surgical Gowns** are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter.

The Aero Blue* Performance Surgical Gowns meet the Level 3 requirements of the AAMI PB70: 2012 Liquid Barrier classifications.

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Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300055864, cn=Elizabeth F. Claverie -S
Date: 2014.06.06 12:04:26 -04'00'

The Aero Blue* Performance Surgical Gowns product codes, sizes, and a brief product description are provided below.

STERILE PRODUCT

Code	Product Description
41732	Aero Blue Performance Surgical Gown, Small/Medium, Sterile
41733	Aero Blue Performance Surgical Gown, Large, Sterile
41734	Aero Blue Performance Surgical Gown, X-Large, Sterile
41735	Aero Blue Performance Surgical Gown, XX-Large, Sterile
41736	Aero Blue Performance Surgical Gown, XXX-Large, Sterile
41724	Aero Blue Performance Surgical Gown, X-Long, Large, Sterile
41726	Aero Blue Performance Surgical Gown, X-Long, X-Large, Sterile

NON-STERILE PRODUCT

Product Code	Product Description
41739	Aero Blue Performance Surgical Gown, Large
41737	Aero Blue Performance Surgical Gown, Large Handi-Bin
41738	Aero Blue Performance Surgical Gown, X-Large, Handi-Bin
41740	Aero Blue Performance Surgical Gown, X-Large
41741	Aero Blue Performance Surgical Gown, XX-Large
41722	Aero Blue Performance Surgical Gown in Overwrap, Large, Handi-Bin
41723	Aero Blue Performance Surgical Gown in Overwrap, X-Large, Handi-Bin
41725	Aero Blue Performance Surgical Gown, X-Long Large
41727	Aero Blue Performance Surgical Gown, X-Long, X-Large